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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,834	03/20/2006	Steffen Goletz	GULDE-59	7472

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,834	GOLETZ ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *74-84* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

1. Prior to setting forth the Restriction Requirement, it is pointed out that applicants have presented the instant claims in improper format (e.g., see claims 81-84). The claims are improperly joined as the various groups indicated below appear to encompass distinct methods of therapy and diagnosis to such an extent that they are considered separately patentable. A method of diagnosing requires a detection step wherein a detectable label is identified or visualized, which is not required by the method of treating. Claims 81-84 do not require this "detection step" and as such are not proper process claims. Therefore, the restriction will be set forth for each of the various groups, irrespectively of the improper format of the claims, because these are not proper process claims.

2. Claims 81-84 are drafted as non-statutory "use" claims under 35 U.S.C. 101 and as such are improper process claims (MPEP 2173.05(q)). For compact prosecution, the claims have been interpreted as set forth below. In response to this restriction requirement, Applicant is required to amend the claims as proper process claims in order to have compact prosecution in the present application.

3. Applicant is advised that claim 80 is drafted as an improper multiple dependent claim because any dependent claim which refers to more than one other claim ("multiple dependent claim ") shall refer to such other claims in the alternative only and a multiple dependent claim shall not serve as a basis for any other multiple dependent claim. See MPEP 608.01(n). In order to have compact prosecution in the instant application and further consideration on the merits, applicant should amend the claim to place the claim in proper dependent form in response to this restriction requirement.

Sequence Requirements

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37

C.F.R. §§ 1.821-1.825. Claim 76 contains sequences that are encompassed by the sequences rules (i.e., an unbranched sequence of four or more defined amino acids) and require sequence identifiers (SEQ ID numbers). Applicant is required to either amend the Figures with the corresponding SEQ ID numbers or alternatively applicant may amend the Brief Description of the Figures (beginning at page 17 of the specification) with the corresponding SEQ ID numbers. Applicant is reminded to check the entire disclosure to ensure that the application is in sequence compliance.

5. Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply (see attached).

6. APPLICANT IS GIVEN THE TIME ALLOTED IN THIS OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six-month statutory period. Direct the response to the undersigned.

Election/Restrictions

7. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 71-79 and 80-84 drawn to a recognition molecule fused or associated with immunoglobulin domains, wherein the recognition molecule binds the core 1 antigen, a method of producing the recognition molecules and a method for treating tumors comprising administering the recognition molecule.

Group II, claims 71-79 drawn to a recognition molecule fused or associated with enzyme molecules, wherein the recognition molecule binds the core 1 antigen.

Group III, claims 71-79 drawn to a recognition molecule fused or associated with interaction domains, wherein the recognition molecule binds the core 1 antigen.

Group IV, claims 71-79 drawn to a recognition molecule fused or associated with domains for stabilization, wherein the recognition molecule binds the core 1 antigen.

Group V, claims 71-79 drawn to a recognition molecule fused or associated with signal sequences, wherein the recognition molecule binds the core 1 antigen.

Group VI, claims 71-79 drawn to a recognition molecule fused or associated with a diagnostic agent such as fluoescent dyes, chelating agents for radioactive labeling or radioisotopes, wherein the recognition molecule binds the core 1 antigen.

Group VII, claims 71-79 drawn to a recognition molecule fused or associated with a therapeutic agent such as toxins, cytolytic agents, chelating agents for radioactive labeling or radioisotopes, wherein the recognition molecule binds the core 1 antigen.

Group VIII, claims 71-79 drawn to a recognition molecule fused or associated with catalytic antibodies, wherein the recognition molecule binds the core 1 antigen.

Group IX, claims 71-79 drawn to a recognition molecule fused or associated with one or more antibodies with different specificity, wherein the recognition molecule binds the core 1 antigen.

Group X, claims 71-79 drawn to a recognition molecule fused or associated with immunomodulators, wherein the recognition molecule binds the core 1 antigen.

Group XI, claims 71-79 drawn to a recognition molecule fused or associated with immunoeffectors, wherein the recognition molecule binds the core 1 antigen.

Group XII, claims 71-79 drawn to a recognition molecule fused or associated with MHC class I or class II antigens, wherein the recognition molecule binds the core 1 antigen.

Group XIII, claims 71-79 drawn to a recognition molecule fused or associated with liposomes, wherein the recognition molecule binds the core 1 antigen.

Group XIV, claims 71-79 drawn to a recognition molecule fused or associated with transmembrane domains, wherein the recognition molecule binds the core 1 antigen.

Group XV, claims 71-79 drawn to a recognition molecule fused or associated with viruses, wherein the recognition molecule binds the core 1 antigen.

Group XVI, claims 71-79 drawn to a recognition molecule fused or associated with cells, wherein the recognition molecule binds the core 1 antigen.

Group XVII, claims 81-84 interpreted as drawn to a method for diagnosing a tumor comprising administering a recognition molecule that binds the core 1 antigen and detecting the bound recognition molecule, for example.

8. In addition, each Group detailed above reads on numerous patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. Applicant(s) must further elect up to ten (10) sequences for examination. It is noted that this is a restriction requirement to up to ten (10) sequences and NOT a species election requirement. Applicant should clearly identify sequences X, Y, and Z, for example, for the elected claims.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121.

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined.

9. The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is considered a recognition molecule fused or associated with immunoglobulin domains, wherein the recognition molecule binds the core 1 antigen.

The special technical feature of Groups II-XVI are a recognition molecule fused or associated with enzyme molecules, interaction domains, domains for stabilization, signal sequences, a diagnostic agent such as fluoescent dyes, chelating agents for radioactive labeling or radioisotopes, a therapeutic agent such as toxins, cytolytic agents, chelating agents for radioactive labeling or radioisotopes, catalytic antibodies, one or more antibodies with different specificity, immunomodulators, immunoeffectors, MHC class I or class II antigens, liposomes, transmembrane domains, viruses, and cells, respectively, that share no common structure, property and function with Group I or any of the other Groups and thus, do not share the same or a corresponding technical feature.

The special technical feature of Group XVII is considered to be a method for diagnosing a tumor comprising administering a recognition molecule that binds the core

1 antigen and detecting the bound recognition. Hence, unity is lacking among groups I-XVII.

Pursuant to 37 C.F.R. 1.475 (d), the ISA/US considers that where multiple products, processes and methods are claimed, *the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto.* Accordingly the main invention (Group 1) comprises a recognition molecule fused or associated with immunoglobulin domains, which is the first product, and the first method of making and using said recognition molecule.

Further pursuant to 37 C.F.R. 1.475 (d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention. Therefore, the groups of inventions above do not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

Accordingly Groups I-XVII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

10. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00

AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643